BC 10.200 - Research Supported by a Department of Defense Component

I. POLICY:

Human research supported by a Department of Defense (DoD) Component is subject to the Federal Policy for the protection of human subjects in research (i.e., the Common Rule). However, because of the DoD culture, organizational structure, and population, additional requirements apply to human subjects' research supported by a DoD Component through a contract, grant, or other arrangement. These requirements are designed to cover risks unique to DoD personnel that differ from civilians in both the conduct of and participation in research. The procedures outlined in this policy ensure that Baystate research supported by a DoD Component complies with DoD regulations governing human research.

II. PURPOSE:

To provide guidance for researchers and Institutional Review Boards (IRB) about special requirements for conducting and reviewing human subjects research involving any Component of the Department of Defense (DoD) or involving recruitment of DoD personnel.

III. SCOPE:

This policy applies to all Baystate Health employees, physicians, students, residents, and others associated with Baystate Health and its entities who are conducting human subject research supported by a Department of Defense Component through a contract, grant, or other arrangement as well as research that involves the DoD (i.e. it is conducted in collaboration with DoD employees, uses DoD facilities, or will intentionally include DoD personnel as experimental subjects). Responsibility for upholding DoD requirements for human subjects' research is shared between researchers and their teams, the health system administration and the DoD.

Department of Defense components include, but may not be limited to:

- Department of Defense
- Navy
- Office of Naval Research
- Naval Academy
- U.S. Naval Observatory
- Army
- U.S. Army Corps of Engineers
- Military Academy (West Point)
- Air Force
- Air Force Academy
- Marines
- Coast Guard
- Uniformed Services University of the Health Sciences
- National Guard
- Missile Defense Agency
- Defense Advanced Research Projects Agency (DARPA)
- Pentagon Force Protection Agency
- Defense Intelligence Agency
- National Geospatial-Intelligence Agency
- National Security Agency
- National War College, National Defense University
- Defense Health Agency
- Defense Acquisition University
- Special Operations Command

IV. DEFINITIONS:

A Department of Defense Component: a military department, defense agency, DOD field activity, or organization within the Office of the Secretary of Defense. DOD Components include but may not be

limited to: Department of Defense, Army, National Guard, Navy, Air Force, Marines, U.S. Army Corps of Engineers.

DOD subjects: This includes any person captured, detained, held, or otherwise under the control of DOD personnel (military, civilian, or contractor employee). Such persons include: Enemy Combatant, Lawful Enemy Combatant, Unlawful Enemy Combatant, Retained Person, and Civilian Internee. In accordance with DoD prohibitions for detainees and prisoners of war as research subjects, Baystate has chosen not to participate in local research recruitment involving detainees and prisoners of war.

DOD Research Involving Interventions or Interactions with Subjects: Research involving a human being as a research subject is an activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Research involving a human being as a research subject is a subset of research involving human subjects. This definition does not include exempt research involving human subjects.

DOD Research Monitor: The research monitor may be identified by an Investigator or appointed by an IRB or Institutional Official (IO) for research involving human subjects determined to involve minimal risk. There may be more than one research monitor (e.g., if different skills or experiences are necessary). The monitor may be an ombudsman or a member of the data safety monitoring board. The Heads of the Office of the Secretary of Defense and DOD Components may waive the requirement to have a research monitor on a case-by-case basis when the inclusion of a research monitor is not necessary to provide additional protections for human subjects. This waiver authority may be delegated to a DOD official, as described in the Component's Human Research Protection Program (HRPP) management plan, but not at or below the position of the institution's DOD IO.

DOD Ombudsman: independent, impartial resource that provides DOD employees worldwide with a safe harbor for informal and confidential dispute resolution.

DOD Minimal Risk: means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or physiological examination or tests. The definition of minimal risk does not include the inherent occupational risks that certain participants face in their everyday life, such as those:

- Encountered by Service members, law enforcement, or first responders while on duty.
- Resulting from or associated with high-risk behaviors or pursuits.
- Experienced by individuals whose medical conditions involve frequent tests or constant pain.

V. PROCEDURES

A. Criteria for IRB Approval Specific to DOD

1) When appropriate, research protocols must be reviewed and approved by the IRB prior to the Department of Defense approval. Consult with the Department of Defense funding Component to see whether this is a requirement.
2) Service members must follow their command policies regarding the requirement to obtain command permission to participate in research involving human subjects while on-duty or off-duty.
3) The disclosure regarding provisions for research-related injury follows the requirements of the DOD Component. The PI is responsible for informing the IRB, in writing, if there

are any additional requirements from the DOD Component regarding the provision of care in the case of a research-related injury.

a. When conducting multisite research, a formal agreement is required to specify the roles and responsibilities of each party including a Statement of Work (SOW) and specific assignment of responsibilities.
b. Surveys performed on Department of Defense personnel must be submitted, reviewed, and approved by the Department of Defense after the research protocol is reviewed and approved by the IRB. When a survey crosses DoD Components, additional review is required.
c. If consent is to be obtained from the research subjects' legal representative, the research must intend to benefit the individual participant.
d. The determination that research is intended to be beneficial to the individual research subject must be made by an IRB.
e. When Investigators are following International Conference on Harmonisation-Good Clinical Practice (ICH-GCP) Element 6 (E6) guidelines, Investigators and research staff must provide all the disclosures and follow the requirements pertaining to consent covered by ICH-GCP(E6).
f. The Investigator and research staff are aware of the specific DOD requirements and have been educated about these requirements.
g. The research does NOT involve prisoners of war or detainees as subjects.
h. The research does NOT involve classified research.
i. The research does NOT involve the testing of chemical or biological agents.
j. If an IRB at a non-DoD institution reviews DoD-supported research, the IRB must consider the scientific merit of the research, including consideration of feasibility of study completion.
k. The IRB may rely on outside experts to provide an evaluation of the scientific merit.

B. DoD Education and Training

DoD requires that investigators complete human research protections training. There may be specific educational requirements or certification required by DOD above the educational requirements required by the institution. The Principal Investigator is responsible for ensuring that all research staff have completed the Baystate required Collaborative Institutional Training Initiative (CITI training). The PI is also responsible for identifying any additional specific educational or certification requirements of the sponsoring DoD Component and should discuss any specific additional DoD educational requirements with their DoD human research protection officer/DoD representative. The PI will ensure that study team members complete any additional training or certification required by the DoD Component. If any additional training requirements pertain to the IRB Chairs, Staff and Members, this information should be shared with the IRB, and the IRB will ensure the requirements are met. The DoD Component may evaluate the training program to ensure that personnel are qualified to perform the research, based on the complexity and risk of the research.

C. Before Initiation of Human Subjects Research

Before initiation of the human subjects' research, the PI must submit to the DoD human research protection officer:

1) Documentation that the DoD-supported human subjects research has been reviewed and approved by an IRB, including scientific merit, amendments, and additional reviews.
2) Documentation of key investigators' human research protection training.
3) IRB-approved protocol documents.
4) Current FWA and IRB registration numbers.
5) If the research has been determined exempt or does not involve human subjects, Investigator must submit institutional documentation of the determination and include all protocol-related documents.

Also before the research involving human subjects can begin, the DoD Component must conduct an appropriate administrative review (required for foreign research, fetal research, genomic data, classified studies, or consent waivers) of DoD-conducted and/or DoD-supported research involving human participants when:

1) Human participants research is conducted in a foreign country, unless conducted by a DoD overseas institution, or only involves DoD-affiliated personnel who are US citizens.
    a. Baystate does not currently conduct foreign research.
2) The research requires a waiver of informed consent (only permissible under DoDI 3216.02 Change 2 if research benefits the subject and is approved by DOHRP)
3) The research is fetal research, as described in the US Title 42 regarding Public Health and Welfare Prohibitions regarding human fetal tissue. Large scale genomic data is collected from DoD-affiliated personnel.
4) The research constitutes classified research involving human participants.
5) The research is required to be approved by the DOHRP.
6) DoD institutions collaborating with non-DoD institutions may rely on a collaborating non-DoD institution's IRB if the following conditions are met:
    a. Each institution engaged in non-exempt human participant research must have a current federal assurance of compliance.
    b. The non-DoD institution's IRB is registered in accordance with federal common rule.
    c. The DoD institution, non-DoD institution, and the non-DoD institution's IRB have a written agreement defining the responsibilities and authorities of each organization in complying with all legal requirements. This agreement must specify that the non-DoD IRB will apply the DoD requirements.
    d. If the research constitutes classified human participant research, the Component Office for Human Research Protections (COHRP), on behalf of the Component's Senior Designated Official, must approve the agreement to rely on the non-DoD institution's IRB.

D. Informed Consent and Criteria for Waiver of Consent

1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative. In addition to the basic and required consent disclosures, consent documents must include:
    - A statement that the DoD or a DoD organization is funding the study.
    - A statement that representatives of the DoD are authorized to review research records.

E. Additional Protections for Privacy and Confidentiality in Research

1) A non-DoD institution conducting human subjects research with DoD support may obtain a Certificate of Confidentiality (CoC) pursuant to Section 241 of Title 42, U.S.C., including genomic data protections (CoC) pursuant to Section 241 of Title 42, U.S.C. A CoC prohibits disclosing or providing, in any federal, State, or local civil, criminal, administrative, legislative, or other proceeding, or to any other person not connected with the research, the name of any individual or any such information, document, or biospecimen that contains identifiable information about the individual, created or compiled for purposes of research. Exceptions to the CoC must be listed in all informed consent documents.
2) When following DoD requirements:
    a. Data or information acquired by the DoD Component under a pledge of confidentiality for exclusively statistical purposes must be used exclusively for statistical purposes and may not be disclosed in identifiable form for any other purpose, except with the informed consent of the respondent.
    b. All studies involving large scale genomic data collected on/from DoD-affiliated personnel will apply an HHS Certificate of Confidentiality pursuant to Section 241 of Title 42, U.S.C., including genomic data protections.

F. Payment for Research

1) Employees of the Department of Defense (including temporary, part-time, and intermittent appointments) may not be able to legally accept payments to participate in research and should check with their supervisor before accepting such payments. Employees of the Department of Defense cannot be paid for conducting research while on active duty.
2) Military personnel will not be paid for research conducted while on duty; however, the personnel can be compensated if involved in the research while not on duty.
    a. Although federal personnel participating as human subjects in DOD-conducted research while on duty may be compensated up to $50 for each blood draw for scientific and research purposes in connection with the care of any person entitled to treatment at government expense, this IRB allows no such compensation (DoD personnel may not be paid while on duty; blood draw compensation capped at $50 under specific conditions) when compensation is otherwise prohibited.
    b. Military personnel can participate in research off-duty; however, they cannot be paid from federal funds for research conducted while off duty.
    c. Non-Federal persons may be compensated for research participation other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research.

G. Recruitment of DoD Affiliated Personnel

If planning to recruit DoD-affiliated personnel as subjects in DoD-supported research, the lead PI must receive command or Component approval to execute the research. In addition, in order to approve research involving DoD-affiliated personnel as human subjects, the IRB or HRPO must determine whether the following requirements have been satisfied:

1) The consent documentation must include, if applicable, potential risks for the revocation of clearance, credentials, or other privileged access or duty.

2) DoD-affiliated personnel, military and civilian supervisors, officers, and others in the chain of command:
    a. Are prohibited from influencing their subordinates to participate in research involving human participants.
    b. Must not be present at any human participant recruitment sessions or during the consent process for DoD-affiliated personnel.
    c. May participate in separate human participant research recruitment sessions.
3) For research involving minimal risk: The IRB has discussed and determined whether to appoint an ombudsman based in part on the subject population, the consent process, and the recruitment strategy.
4) For greater than minimal risk research involving DoD-personnel, when recruitment and consent occurs in a group setting, the IRB must appoint an ombudsperson. The ombudsperson:
    a. Must not have a conflict of interest with the research or be a part of the research team.
    b. Must be present during the HSR recruitment, monitoring that the recruitment and informed consent explain that participation is voluntary and that the information provided about the research is consistent with the IRB- approved script and materials, including digitally provided materials.
    c. Should be available to address DoD-affiliated personnel's concerns about participation.
5) In conducting or supporting clinical research, the Secretary of Defense shall ensure that:
    d. Women who are members of the Armed Forces are included as participants in each project of such research.
    e. Members of minority groups who are members of the Armed Forces are included as participants of such research.
    f. The Secretary of Defense may waive these requirements regarding women and members of minority groups with respect to a project of clinical research if the Secretary determines that the inclusion, as participants in the project, of women and members of minority groups, respectively:
        i. Is inappropriate with respect to the health of the participants,
        ii. Is inappropriate with respect to the purpose of the research, or
        iii. Is inappropriate under such other circumstances as the Secretary of Defense may designate.

H. Research with impaired decision-making capacity individuals

1) If the research involves interventions or interactions with individuals with impaired decision-making capacity, there must be an anticipated direct benefit to the subject.

I. Research Involving Pregnant Women and Children

1) Research involving pregnant women and children are subject to the Department of Health and Human Services (DHHS) Subparts B and D.

a. Subpart B – Research with Pregnant Women and Fetuses

i. For purposes of applying Subpart B, the phrase "biomedical knowledge" shall be replaced with "generalizable knowledge."

ii. The applicability of Subpart B is limited to research involving pregnant women as participants in research that is more than minimal risk and included interventions or invasive procedures to the woman or the fetus or involving fetuses or neonates as participants.

iii. Fetal research must comply with the Public Health and Welfare Prohibitions regarding human fetal tissue.

b. Subpart D – Research with Children

i. Research involving children cannot be exempt.

J. Research Involving More Than A Minimal Risk

1) Research Monitor

a. For research involving more than minimal risk, an independent research monitor has been appointed by name who:
b. Has expertise consonant with the nature of risk(s) identified within the research protocol.
c. Is independent of the team conducting the research involving human subjects.
d. Has authority to stop a research in progress, remove individual subjects from research, and take necessary steps to protect the safety and well-being of subjects until the IRB can assess the monitor's report.
e. Will promptly report his/her observations and findings to the IRB or other designated official.
f. Has an IRB approved written summary of duties, authorities, and responsibilities based on specific risks or concerns about the research. The duties of the research monitor shall be determined on the basis of specific risks or concerns about the research. The research monitor may perform oversight functions (e.g., observe recruitment, enrollment procedures, and the consent process for individuals, groups or units; oversee study interventions and interactions; review monitoring plans and UPIRTSO reports; and oversee data matching, data collection, and analysis) and report their observations and findings to the IRB or a designated official. The research monitor may discuss the research protocol with the Investigators, interview human subjects, and consult with others outside of the study about the research. The research monitor shall have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor's report. Research monitors shall have the responsibility to promptly report their observations and findings to the IRB or other designated official.

K. Non-Compliance or Research Misconduct

1) Any determinations of serious or continuing non-compliance of DoD supported research must be promptly reported to the DoD human research protection officer (HRPO). Records maintained that document compliance or non-compliance with Department of Defense requirements shall be made accessible for inspection and copying by representatives of the Department of Defense at reasonable times and in a reasonable manner as determined by the supporting DOD Component.
2) Department of Navy (DoN)-sponsored research has additional requirements which must be references as appropriate.

L. Additional Reporting Requirements by Investigator to DOD

1) The following shall be promptly reported (within 30 days) to the Department of Defense Human Research Protections Officer by the Investigator:
    a. When significant changes to the research protocol are approved by the IRB.

b. Decreased benefit or increased risk to participants in greater than minimal risk research.
c. Addition of vulnerable populations as participants.
d. Addition of DoD-affiliated personnel as participants.
e. The results of the IRB continuing review.
f. Change of reviewing IRB.
g. When a previously enrolled human participant becomes pregnant, or when the researcher learns that a previously enrolled human participant is pregnant, and the protocol was not reviewed and approved by the IRB in accordance with Subpart B.
h. When a previously enrolled human participant becomes incarcerated, or when the researcher learns that a previously enrolled human participant is incarcerated, and the protocol was not reviewed and approved by the IRB in accordance with Subpart C.
i. A DoD-supported study's closure.
j. When the organization is notified by any Federal department, agency or national organization that any part of the HRPP is under investigation for cause involving a DOD-supported research protocol.
k. Any unanticipated problems involving risks to participants or others for any DoD-supported research must be promptly (no longer than within five days) reported to the DoD Office for Human Research Protections.

M. Additional Reporting Requirements by IRB

1) The following must be promptly reported to the Directorate of Human Research Protections (DOHRP):
    a. Reports of audits of DoD-conducted or DoD-supported human participant research by another federal or state agency, official governing body of a Native American or Alaskan native tribe, other official entity, or foreign government, within 5 business days of discovering that such audit reports exist.
    b. Allegations of serious or continuing noncompliance related to Human Subject Research (HSR) that are substantiated by investigation, and subsequent actions taken based on the findings, within five business days of completion of the report.
    c. Unanticipated problems involving risks to human participants or others and subsequent actions taken based on the findings, within five business days of completion of the report.
    d. Any suspension or termination of DoD-supported research must be promptly (no longer than within five days) reported to the DoD Office for Human Research Protections.
        i. Substantiated allegations related to classified HSR must be reported immediately (less than five days) to the DOHRP.

POLICY REFERENCES

- DoD Regulation (32CFR219): Department of Defense (DoD) Regulation, Title 32 CFR Part 219: "Protection of Human Subjects", 19 January 2018.
- 42 U.S.C. 241- Research and Investigations Generally
- 42 U.S.C. 289g-12 - Prohibitions regarding human fetal tissue
- 10 USC 980

- DoD Directive 3216.2
- SECNAVINST 3900.39D
- OPNAVINST 5300.8B
- DoD Dual Compensation Act, 24 U.S.C 301

- Common Rule (45CFR46): Department of Health and Human Services (DHHS) Regulation, Title 45 CFR Public Welfare, Part 46: "Protection of Human Subjects", 21 January 2019.
- Consult SECNAV Instruction: Secretary of the Navy Instruction, SECNAVINST 3900.39E CH-1 (May 29, 2018, reaffirmed 2025), "Human Research Protection Program", 29 May 2018. SECNAVINST 3900.39E CH-1 (May 29, 2018, reaffirmed 2025).Department of Defense (DoD) Instruction 6200.02, “Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs, February 27, 2008.
- DoD Instruction 3216.02 Change 2 (July 25, 2025), “Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and Supported Research”, Effective April 15, 2020.
- International Conference on Harmonization – Good Clinical Practice (E6) GuidelinesUnder Secretary of Defense Memorandum, HA Policy 05-003, March 28, 2005; “Policy for Protection of Human Subjects in Department of Defense Sponsored Research” Department of Defense Instruction 1100.13, November 21, 1996, “Surveys of DoD Personnel” Section 980 of Title 10, United States Code

APPROVALS

		Date:
Approved:	BH Policy Management Committee	1/27/2026
Policy Owner: (department name)	Office of Research	
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